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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

June 19, 1998

WARNING LETTER
CHI-25-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Amy Kramer, Owner
MWM, LLC
8135 N. Monticello Ave.
Skokie, IL 60076

Dear Ms. Kramer:

This letter is in reference to your firm's marketing and distribution of the products Phenylpropanolamine HCL (PPA), L-Tyrosine, Vitamin C, and Vitamin B-6.

Your product, Phenylpropanolamine HCL, is labeled as an alternative to the combination of the prescription drugs fenfluramine and phentermine, which is commonly known as "Fen-Phen" and to the prescription drugs mazindol and diethylpropion. These prescription drugs are all intended to treat obesity. Labeling your product as an alternative to Fen-Phen (fenfluramine and phentermine), or to other prescription obesity drugs, represents it as intended for the same uses as the prescription drugs. Thus, you are representing Phenylpropanolamine HCL as a treatment for obesity. In this regard, Phenylpropanolamine HCL is a drug as defined in Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). Labeling is not limited to the immediate product containers but includes all promotional literature which you distribute in connection with your products.

Objectionable claims for PPA include the following:

> "Immediate release PPA, like Phen/Fen and Redux, can result in significant weight loss."
> "...PPA like Phen/Fen, has the added benefit of helping maintain weight loss long-term."
>
> "The average weight loss with prescription pills is approximately 15 percent of body weight."
>
> "PPA seems roughly as effective as prescription diet pills."
>
> "How effective is PPA compared to prescription diet pills like Fen-Phen or Redux?" This question is followed by three paragraphs comparing PPA to Fen-Phen, Redux, mazindol, and diethylpriopion.

In addition, the MWM Internet web site discusses "treatments for obesity," refers to Phentermine and Fenfluramine, and includes numerous favorable comparisons and references to Phen/Fen or prescription diet pills. The MWM home page is titled "The Phen/Fen Alternative Diet" while another page is titled "Am I Obese."

"Phenylpropanolamine HCL" is also a "new drug" under Section 201(p) of the Act based on: 1) Promotion of your product as an equivalent alternative to various prescription obesity drugs, and 2) The lack of any evidence that this product is generally recognized as safe and effective for the treatment of obesity.

Since this drug is a "new drug," it may not be legally marketed in the United States without an approved new drug application [Section 505(a)of the Act]. This drug is also misbranded because its labeling fails to bear adequate directions for use [Section 502(f)(1) of the Act] and the labeling is false and misleading [Section 502(a)] since it (1) suggests that these products are safe and effective for their intended uses, when in fact, this has not been established, (2) "PPA is approved for weight loss by the United States Food and Drug Administration (FDA)." This statement is false in that no such approval exists and (3) "PPA is safer than aspirin, acetaminophen...and ibuprofen." This statement is misleading in that it represents unsubstantiated safety comparison between two separate classes of active ingredients.

Further, your products, PPA, L-Tyrosine, Vitamin C, and Vitamin B-6, are misbranded in that they are not prescription drug products and their labeling includes a prescription drug legend which they are not entitled to bear [Section 501(b)(4)].

In addition, your products L-Tyrosine, Vitamin C, and Vitamin B-6 are promoted for use as adjuncts to your PPA product and are intended to enhance the effectiveness of the PPA. As PPA is intended for use in the treatment of obesity, this may also imply that these products are also intended for use in treating obesity. Such claims may cause your products to be misbranded in that the safety and effectiveness of these products as an adjunct to PPA or in the treatment of obesity have not been established.

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provide for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to The Food and Drug Administration, Chicago District Office, attention of George F. Bailey, Compliance Officer.

Sincerely,

Raymond V. Mlecko
District Director